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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,149	06/22/2001	Peter W.J. Hinchliffe	BSMT117345	8108

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EXAMINER

RODRIGUEZ, CRIS LOIREN

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 06/12/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K

# Office Action Summary

Application No.

09/888,149

Applicant(s)

HINCHLIFFE, PETER W.J.

Examiner

Cris L. Rodriguez

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-- Th MAILING DATE f this communication appears on th cover sh et with the correspondenc addr ss --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-8, 10-12, 17, 20, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 10-12, 17, 20, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 2001 and 07 April 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 07 April 2003 is: a) ☒ approved b) ☒ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

See Drawings section in office action.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14. 6) ☐ Other: \_\_\_\_\_

DETAILED ACTION

*Information Disclosure Statement*

1. The information disclosure statement filed July 2, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires **a legible copy of each U.S. and foreign patent**; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Please submit copies of the references in order to be considered.

*Drawings*

2. The corrected or substitute drawings were received on April 7, 2003. These drawings are approved in part. Figure 1 is approved. Figure 4 is not approved and is being objected below.

3. The drawings are objected to under 37 CFR 1.83(a) because figure 2 and 4 fail to show a rotatable thrombectomy wire as described in the specification, specifically as set forth on page 6 lines 15-19. Figures 2 and 4 show that balloon 20,20' and J-tip 24 is part of the catheter 12, instead of showing the rotatable thrombectomy wire. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

*Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1-4, and 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1, there is no positive recitation for "the wire".

*Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-4, 6-8, 10-12, 17, 20, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shulze (US 6,056,721) in view of Barry et al (US 6,183,487).

Shulze discloses an angioplasty catheter (figs. 2-8) with at least three axially non-communicating passages, a guidewire lumen 28d, a guidewire 22, a first balloon 150 (fig. 8) and a second balloon 146. The second balloon can be made of a low compliance angioplasty balloon. Shulze also recognizes that in addition to the physical enlargement of flow passageways **by mechanical displacement of deposits**, modern techniques may include the use of therapeutics medicines. However, Shulze fails to disclose a rotatable guidewire for performing mechanical thrombectomy, and moot to the second balloon being made of PET (a low compliance material).

Barry teaches a guidewire 225 (fig. 16)<sup>1</sup> extending coaxially through the burr. The wire may be keyed or coupled to the burr such that the wire and burr spin simultaneously for material removal in a stenosed vessel. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute Shulze's

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guidewire with the one shown in Barry. Doing so would have had a rotatable wire for performing mechanical thrombectomy and removing material from a stenosed vessel. Furthermore, the selection of a well known material has been rendered as an obvious design choice, since the selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). In this case, PET as a low compliance material for the angioplasty balloon.

### Response to Arguments

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.


- In regards to applicant's arguments that figures 2 and 4 do not illustrate the rotatable wire since it is fully contained within the catheter and not yet advanced, this statement is incorrect. The specification describes that the J-tip is in the rotatable wire and not in the catheter as shown in these figures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

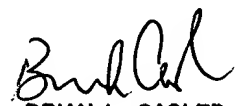
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

June 6, 2003



Cris L. Rodriguez  
Examiner  
Art Unit 3763



BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700